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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,270

12/02/2003

Karl Gauglitz

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EXAMINER

STOKLOSA, JOSEPH A

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/726,270

Applicant(s)

GAUGLITZ ET AL.

Examiner

Joseph Stoklosa

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on 4/24/2007.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 9, 12-13, 21-22, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slettenmark et al. (US 5,344,432) in view of Hammon III et al. (US 6,037,715) in view of De Lucia (US 3,604,870). Slettenmark et al. discloses the claimed invention, an implantable device [column 1, line 50] with a sealed housing [column 2, line 36], the device wherein the plurality of electrical components includes a defibrillator [column 2, line 51], and the device wherein the gas mixture includes one of any combination of helium, argon, oxygen, and nitrogen [column 1, line 57], a method for assembling the device [column 2, line 27], except for the plurality of electrical components disposed within the housing and including at least one pair of adjacent electrically conductive paths wherein the paths are separated by a distance less than approximately 0.01 inches, a gas mixture of at least 1 percent sulfur hexafluoride disposed within the housing, the device of claim 1 wherein the paths are separated by a

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distance less than approximately 0.004 inches (claim 4), a method wherein introducing the gaseous mixture includes enveloping the plurality of electrical components in an atmosphere of greater than approximately 70 percent sulfur hexafluoride (claims 2 and 13), it is known to use a gas mixture that includes at least one of any combination of helium, argon, oxygen and nitrogen; and a gas mixture having a dielectric constant greater than unity disposed within the housing wherein the gas mixture includes greater than 1 percent sulfur hexafluoride.

4. Hammon III, et al. teaches that it is known to use a plurality of electrical components disposed within the housing and including at least one pair of adjacent electrically conductive paths wherein the paths are separated by a distance less than approximately 0.01 inches, as set forth in [column 4, line 31] to provide for a smaller relay gap for the path of adjacent electrically conductive path, that it is known to use conductive paths that are separated by a distance less than 0.004 inches as set forth in [column 4, line 31] to provide a smaller relay gap and as a result a smaller device. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device and method as taught by Slettenmark with a plurality of electrical components disposed within the housing and including at least one pair of adjacent electrically conductive paths wherein the paths are separated by a distance less than approximately 0.01 inches, as taught by Hammon et al. since such a modification would provide an implantable medical device with a smaller relay gap for the path of adjacent electrically conductive path, that it is known to use conductive paths that are separated

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by a distance less than 0.004 inches as set forth in [column 4, line 31] to provide a smaller relay gap and as a result a smaller device.

5. De Lucia teaches that it is known to use a gas mixture of at least 1 percent sulfur hexafluoride disposed within the housing, as set forth in [column 2, line 64] that it is known to use a gas mixture of at least 70 percent sulfur hexafluoride as set forth in [column 2, line 64] to provide greater dielectric properties; that it is known to use the gas mixture includes at least one of any combination of helium, argon, oxygen and nitrogen as set forth in [column 2, line 64] to provide for an environment of inert gas insulation, a gas mixture having a dielectric constant greater than unity disposed within the housing [column 2, line 43] wherein the gas mixture includes greater than 1 percent sulfur hexafluoride [column 2, line 64] to provide a strong dielectric gas mixture to prevent breakdown of electrical components.

6. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device and the method as taught by Slettenmark, with a gas mixture of at least 1 percent sulfur hexafluoride disposed within the housing, that it is known to use a gas mixture of at least 70 percent sulfur hexafluoride as taught by De Lucia, since such a modification would provide greater dielectric properties to prevent breakdown of electrical components; that it is known to use the gas mixture includes at least one of any combination of helium, argon, oxygen and nitrogen as set forth in [column 2, line 64] to provide for an environment of inert gas insulation, a gas mixture having a dielectric constant greater than unity disposed within the housing [column 2,

line 43] wherein the gas mixture includes greater than 1 percent sulfur hexafluoride [column 2, line 64] to provide a strong dielectric gas mixture.

7. Claims 6-8, 23-25, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slettenmark in view of Hammon et al., in view of De Lucia, and further in view of Jabagchourian et al. (US 4,506,244).

8. Slettenmark in view of Hammon et al., in view of De Lucia discloses the claimed invention, as stated above, except for the pressure of the gas mixture being maintained at a pressure greater than one atmosphere, the gas mixture is maintained at a pressure greater than 0.1 pounds per square inch gage, and that the gas mixture is maintained at a pressure less than approximately 5.0 pounds per square inch gage. Jabagchourian et al. teaches that it is known to use maintain pressure of the gas mixture at greater than one atmosphere, as set forth in [column 5, line 16], device wherein the gas mixture is maintained at a pressure greater than 0.1 pounds per square inch gage [column 4, line 42; and column 5, line 16], and the device wherein the gas mixture is maintained at a pressure less than approximately 5.0 pounds per square inch gage [column 4, line 42; and column 5, line 16], to provide for stable pressure within the housing for optimal dielectric properties. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device and method for assembling the device as taught by Slettenmark in view of Hammon et al., in view of De Lucia, with pressure of the gas mixture being maintained at a pressure greater than one atmosphere, the gas

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mixture is maintained at a pressure greater than 0.1 pounds per square inch gage, and that the gas mixture is maintained at a pressure less than approximately 5.0 pounds per square inch gage as taught by Jabagchourian et al., since such a modification would provide the device and method with pressure of the gas mixture being maintained at a pressure greater than one atmosphere, the gas mixture is maintained at a pressure greater than 0.1 pounds per square inch gage, and that the gas mixture is maintained at a pressure less than approximately 5.0 pounds per square inch gage for providing for stable pressure within the housing for optimal dielectric properties.

9. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slettenmark in view of Hammon et al., in view of De Lucia, and further in view of Lingal et al. (US 2,757,261).

10. Slettenmark in view of Hammon et al., in view of De Lucia disclose the claimed invention except for a breakdown voltage between the adjacent electrically conductive paths is greater than approximately 1000 volts and a breakdown voltage between the adjacent electrically conductive paths is greater than approximately 1800 volts. Lingal et al. teaches that it is known use a device with a break down voltage between the adjacent electrically conductive paths is greater than approximately 1000 volts and a breakdown voltage between the adjacent electrically conductive paths is greater than approximately 1800 volts as set forth in [column 3, line 28] to provide a greater breakdown voltage in an implantable device to prevent device failure. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the

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device as taught by Slettenmark in view of Hammon et al. in view of De Lucia, with a breakdown voltage between the adjacent electrically conductive paths is greater than approximately 1000 volts and a breakdown voltage between the adjacent electrically conductive paths is greater than approximately 1800 volts as taught by Lingal et al., since it would provide the device with a breakdown voltage between the adjacent electrically conductive paths is greater than approximately 1000 volts and a breakdown voltage between the adjacent electrically conductive paths is greater than approximately 1800 volts for providing a greater breakdown voltage within an implantable device.

11. Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slettenmark in view of Hammon et al. in view of De Lucia, and further in view of Glauser et al. (US 6,894,246)

12. Slettenmark in view of Hammon et al. in view of De Lucia disclose the claimed invention except for a method wherein sealing the housing includes welding the housing in an argon atmosphere, a method wherein introducing the gaseous mixture includes: drawing a first vacuum in the housing; injecting a first atmosphere into the housing; drawing a second vacuum in the housing; and injecting a second atmosphere into the housing wherein the second atmosphere includes a mixture of helium, a method of wherein the first atmosphere differs from the second atmosphere, a method of wherein at least one of any combination of injecting the first atmosphere and injecting the second atmosphere includes injecting an atmosphere having greater than approximately 85 percent nitrogen, a method wherein at least one of any combination of

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injecting the first atmosphere and injecting the second atmosphere includes injecting an atmosphere having greater than approximately 85 percent sulfur hexafluoride, a method further including purging the interior of a contaminant gas, and a method wherein purging includes flushing with at least one of any combination of nitrogen and sulfur hexafluoride. Glauser et al. teaches that it is known to use a method wherein sealing the housing includes welding the housing in an argon atmosphere [column 5, line 51] to provide, a method wherein introducing the gaseous mixture includes: drawing a first vacuum in the housing; injecting a first atmosphere into the housing; drawing a second vacuum in the housing; and injecting a second atmosphere into the housing wherein the second atmosphere includes a mixture of helium [column 3, line 41-55;], a method of wherein the first atmosphere differs from the second atmosphere, a method of wherein at least one of any combination of injecting the first atmosphere and injecting the second atmosphere includes injecting an atmosphere having greater than approximately 85 percent nitrogen [column 5, line 55], a method wherein at least one of any combination of injecting the first atmosphere and injecting the second atmosphere includes injecting an atmosphere having greater than approximately 85 percent sulfur hexafluoride [column 5 line 55; column 6, line 33], a method further including purging the interior of a contaminant gas[column 6 line 15], and a method wherein purging includes flushing with at least one of any combination of nitrogen and sulfur hexafluoride [column 5, line 6] to provide a method of assembling an implantable device. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method as taught by Slettenmark in view of Hammon et al. in view of De Lucia with

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a method wherein sealing the housing includes welding the housing in an argon atmosphere, a method wherein introducing the gaseous mixture includes: drawing a first vacuum in the housing; injecting a first atmosphere into the housing; drawing a second vacuum in the housing; and injecting a second atmosphere into the housing wherein the second atmosphere includes a mixture of helium, a method wherein the first atmosphere differs from the second atmosphere, a method wherein at least one of any combination of injecting the first atmosphere and injecting the second atmosphere includes injecting an atmosphere having greater than approximately 85 percent nitrogen, a method wherein at least one of any combination of injecting the first atmosphere and injecting the second atmosphere includes injecting an atmosphere having greater than approximately 85 percent sulfur hexafluoride, a method further including purging the interior of a contaminant gas, and a method wherein purging includes flushing with at least one of any combination of nitrogen and sulfur hexafluoride as taught by Glauser, since such a modification would provide a method wherein sealing the housing includes welding the housing in an argon atmosphere, a method wherein introducing the gaseous mixture includes: drawing a first vacuum in the housing; injecting a first atmosphere into the housing; drawing a second vacuum in the housing; and injecting a second atmosphere into the housing wherein the second atmosphere includes a mixture of helium, a method wherein the first atmosphere differs from the second atmosphere, a method wherein at least one of any combination of injecting the first atmosphere and injecting the second atmosphere includes injecting an atmosphere having greater than approximately 85 percent

nitrogen, a method wherein at least one of any combination of injecting the first atmosphere and injecting the second atmosphere includes injecting an atmosphere having greater than approximately 85 percent sulfur hexafluoride, a method further including purging the interior of a contaminant gas, and a method wherein purging includes flushing with at least one of any combination of nitrogen and sulfur hexafluoride for providing a method of assembling an implantable device.

Response to Arguments

13. Applicant's arguments filed 4/24/2007 have been fully considered but they are not persuasive.

14. Applicant argues that the combination of the Hammon reference is non-analogous art. In response to applicant's argument that Hammon is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Hammon teaches a solution for the problem Slettenmark aims to solve, in creating an implantable device, where minimizing a spark gap, as disclosed in Hammon, is necessary for the purpose of minimizing the size of the device so that it would be suitable to be implanted in a patient.

15. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

16. Applicant argues that De Lucia does not teach an implantable defibrillator system; however, it is not necessary for De Lucia to teach an implantable defibrillator, because Examiner relies upon Slettenmark to teach an implantable medical device. De Lucia simply teaches the gas mixture containing 1% sulfur hexafluoride. In addition, Applicant acknowledges that De Lucia does not teach away from non-external, implantable, defibrillators in Amendment received 4/24/2007, Page 10. Applicant cannot interpret the De Lucia reference as teaching away and teaching an external defibrillator system, simply because De Lucia does not explicitly state implantable defibrillator system or even disclosing an external embodiment.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Stoklosa whose telephone number is 571-272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joseph Stoklosa
Examiner
Art Unit 3762


GEORGE R. EVANOFF
PRIMARY EXAMINER

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